ALLIANCE GROUP MEETING

November 3, 2016

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Agenda

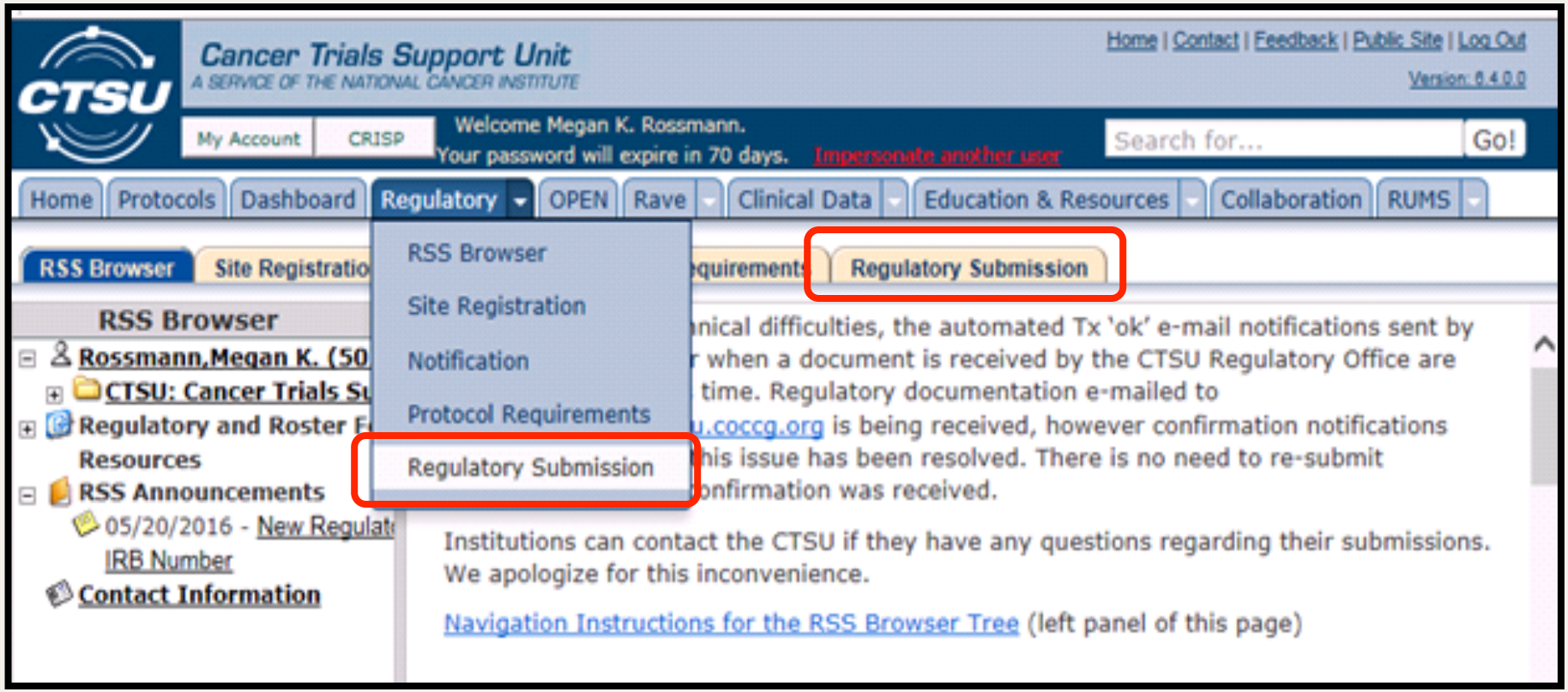
- Regulatory Submission Portal
- Initiatives
  - National Coverage Analysis
  - Site Audit Reporting
  - Ongoing Initiatives
- Public Contact Information
- Website Updates
  - CRISP
  - Online Agent Ordering
  - IROC Credentialing Form

REGULATORY SUBMISSION PORTAL

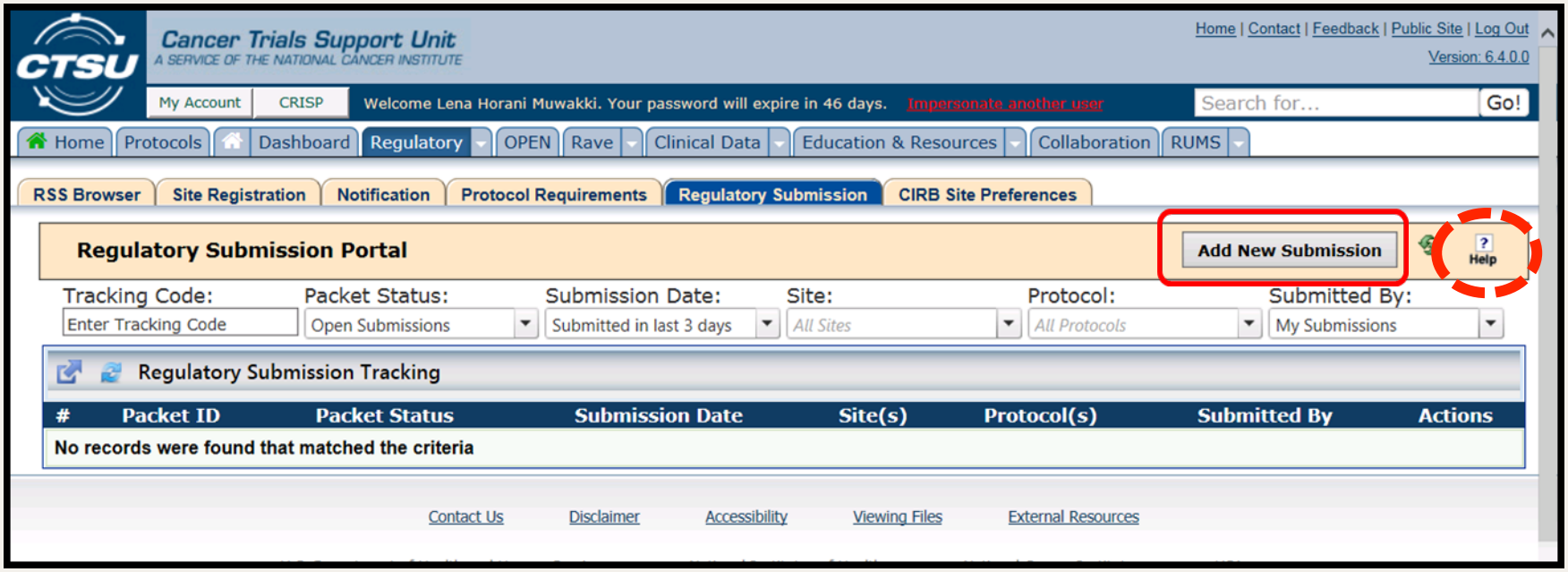
Regulatory Submission Portal

- Allows regulatory documents to be sent by:
  - Website upload, *or*
  - Fax or Email with Barcode Cover Page.
- Streamlined communication
  - Web-tracking of submissions with tracking ID numbers and codes.
  - View images of submissions and monitor progress with real-time status updates.
- Ability to submit and access records for institutions to which users are affiliated on a Network roster as well as for their parent and child sites.

Where is the Regulatory Submission Portal?

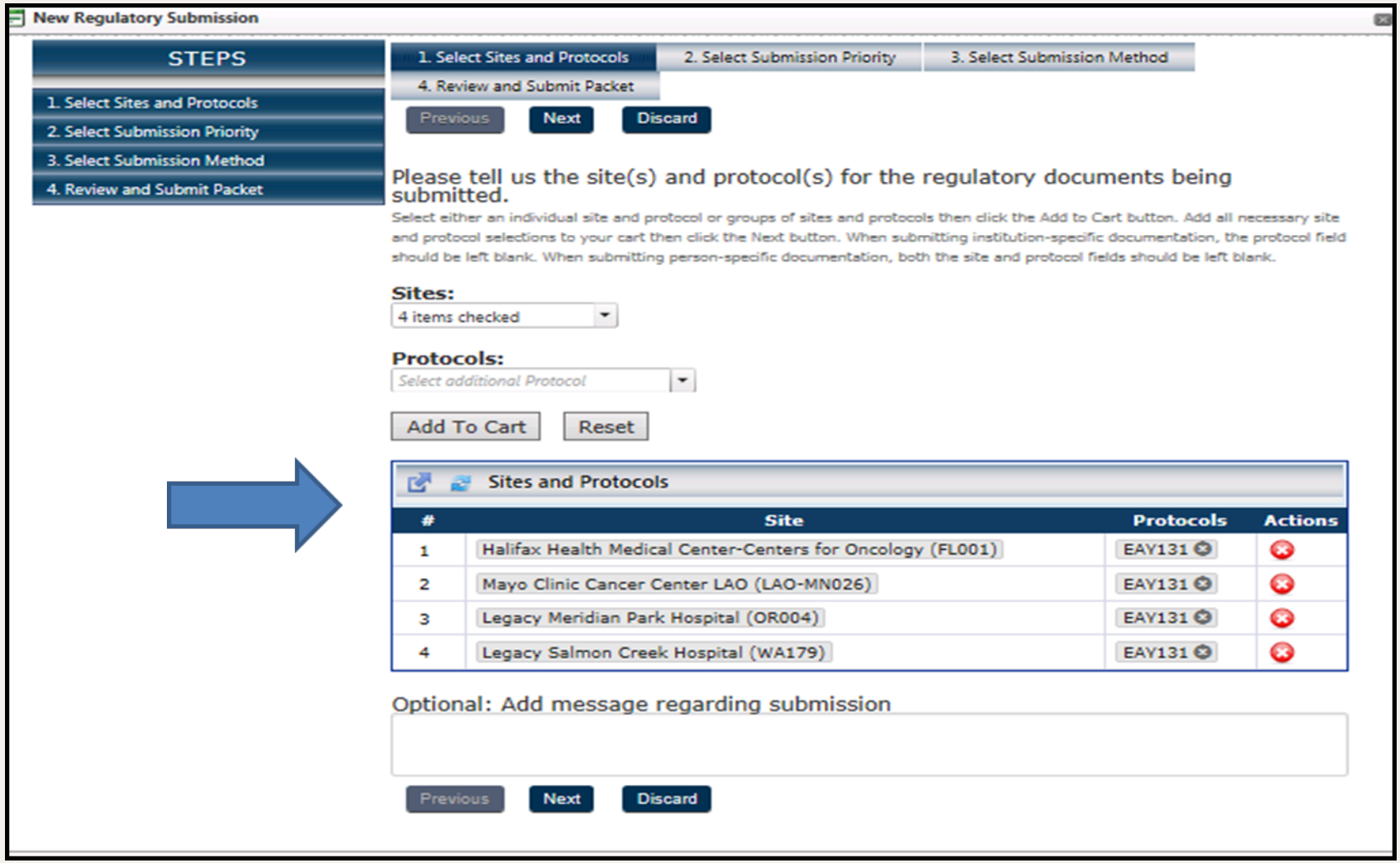


Submitting your Regulatory Submission

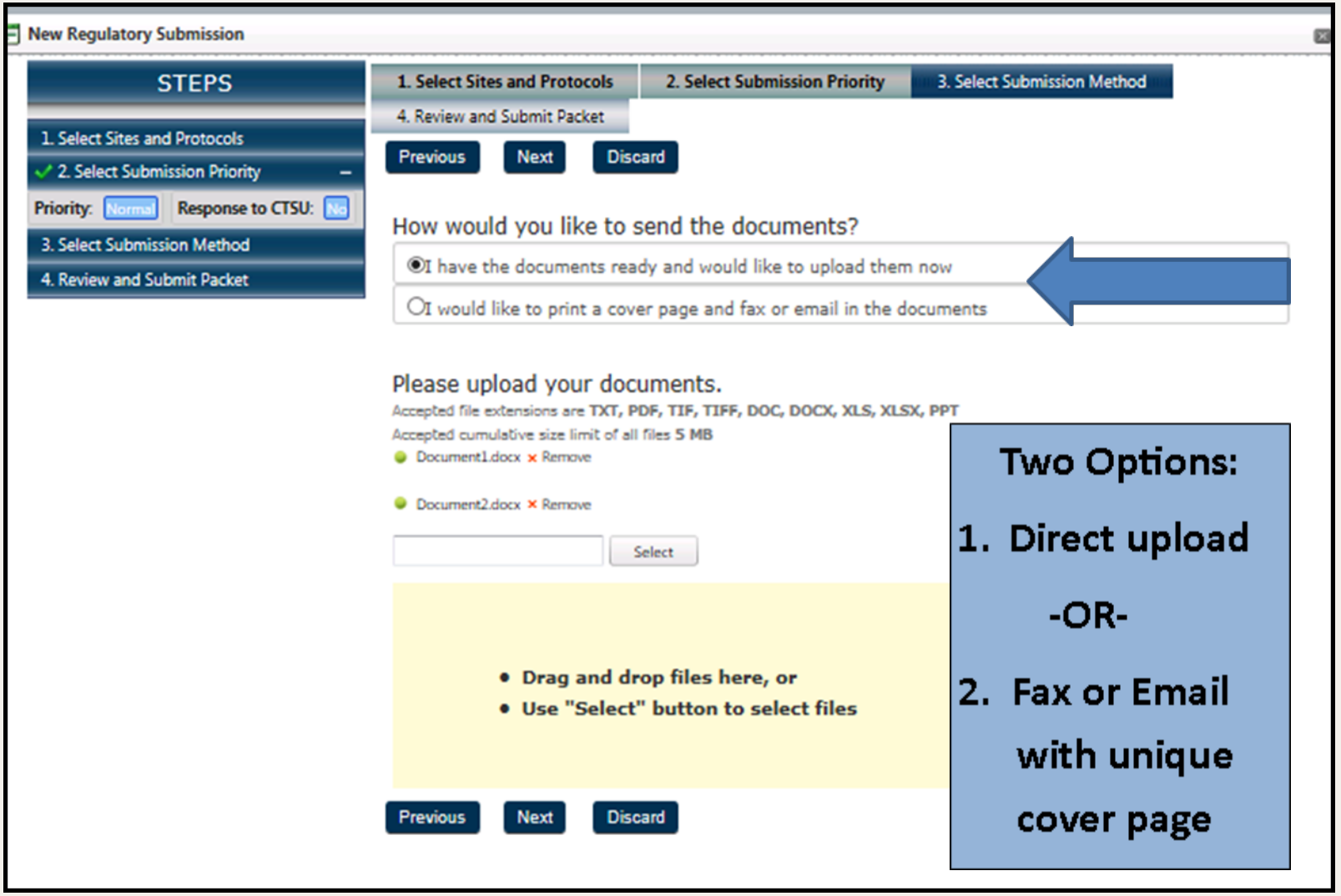


For complete instructions on using the Portal including a list of all "Packet Status" types, review the Regulatory Submission Portal User Guide, by clicking the Help Icon indicated above.

Select Sites and Protocols



Select Submission Method



Example of Email/Fax Submission Confirmation Page

The cover page has a special barcode and must accompany your submission.
The first page of the cover sheet outlines instructions for submission, including the fax number and email address to send submissions.
IMPORTANT NOTE: This fax number and email address are new and do not match the fax and email utilized for non-Portal regulatory submissions.

Regulatory Submission Portal Helpful Tips

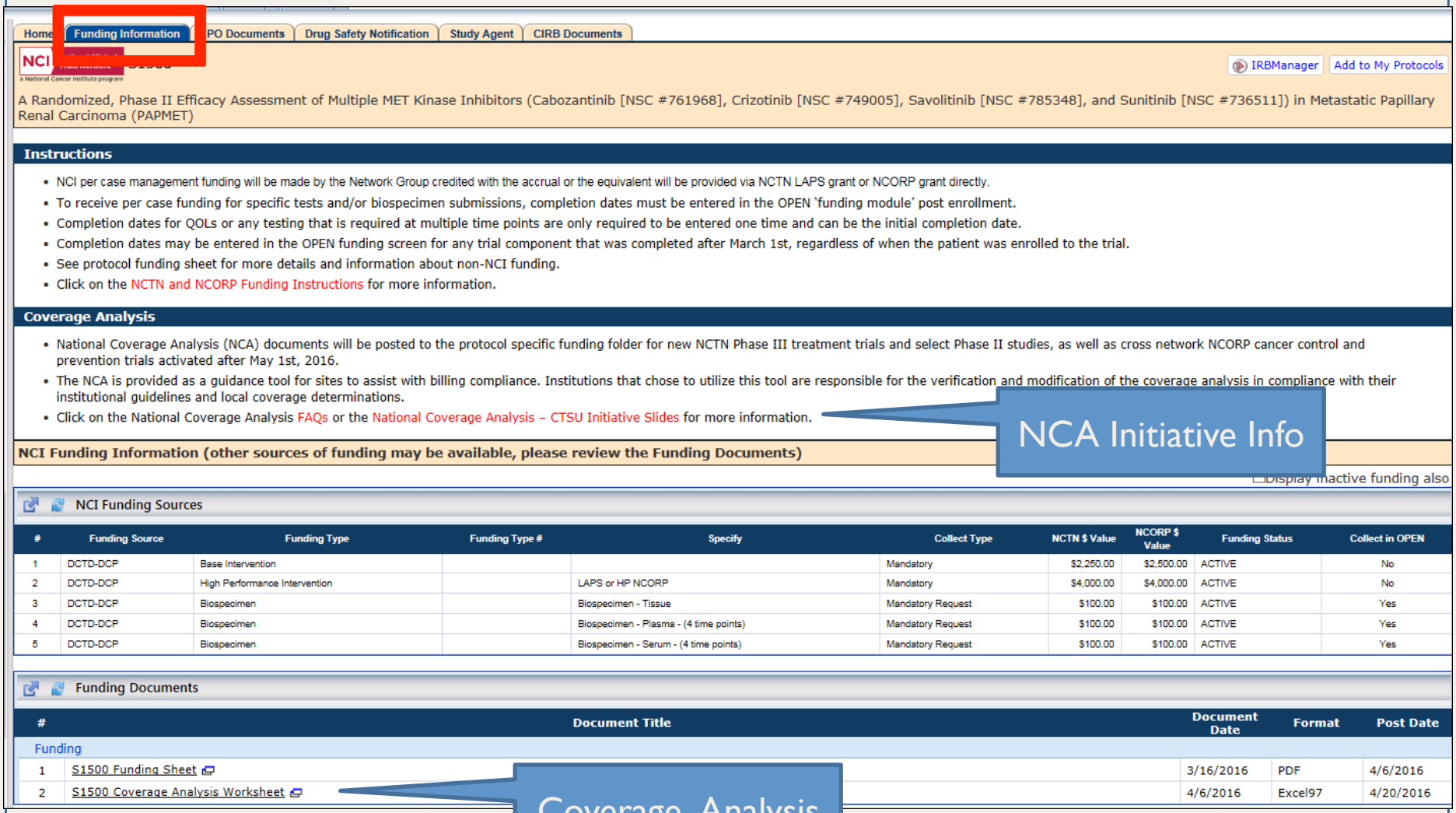
- **File Format:** due to technical limitations files with the following characteristics will NOT be accepted:
  - Exceeding 20MB in size;
  - PDF files containing electronic signature fields;
  - Files with more than one extension (e.g. FileName1.pdf.jpg);
  - File names containing spaces (names must be composed of alpha and numeric characters and underscores);
  - Zip files;
  - Inclusion of an e-mail imbedded with attachments;
  - File names exceeding 35 characters in total; *and*
  - File extensions that do not accurately reflect the type of file (e.g. a text file has a .pdf extension).

INITIATIVES

National Coverage Analysis (NCA) Initiative

- NCA is a review of all tests, procedures and interventions associated with a clinical trial to determine which are 'billable' to a third party
  - Provided as guidance documents to assist sites with billing compliance;
  - Developed using NCCN guidelines and Medicare coverage determinations; *and*
  - Developed in collaboration with the NCTN lead groups, NCORP research bases and billing compliance consultant.
- NCAs are developed and maintained for NCTN Phase III treatment trials, select Phase II studies and cross network NCORP cancer control and prevention trials.
- New and amended NCAs are announced in the CTSU Bi-Monthly Broadcast.
- NCAs and education materials are located under the protocol-specific funding tabs of the CTSU website.
- Sites are responsible for verification and modification of the NCA in compliance with institutional guidelines and local coverage determinations.

Where to Find NCA Information



Site Audit Reporting

- Developed with the Clinical Trials Monitoring Branch (CTMB) to provide a more uniform, streamlined approach for accessing Source Data Verification (SDV) in Medidata Rave®.
- Goals:
  - Ability to electronically capture SDV activity in Rave;
  - Support transition from a paper-based site audit process to unified electronic process, creating a pathway to risk-based monitoring/ auditing; *and*
  - Develop uniform workflow for Lead Protocol Organizations (LPOs) on pre/post SDV activities (e.g., sending study invitations to monitors, managing audit close-out, and enabling cross-group auditing).
- Pilot Phase with Alliance, NRG and SWOG is wrapping up at the end of this year.

Ongoing Initiatives

- Data Quality Portal
  - Allows sites to view data delinquency and queries across Rave-supported trials (if Rave Calendaring is implemented);
  - Alliance has participated in the piloting activities;
  - Production roll out is planned for the end of this year, more information will be available in the bimonthly broadcast;
  - A user guide will be available for sites once the DQP is in production.
- Serious Adverse Event (SAE) Integration
  - Allows entry of Adverse Events (AEs) in Rave with real-time recommendation for completing an expedited report based on protocol specific rules.
  - A071102 is part of the current pilot. A second pilot will begin in the next few months. This pilot with launch the integration between Rave and CTEP-AERS

PUBLIC CONTACT INFORMATION

Public Contact Information (1)

- Public research contact information is collected on participating site/protocol Principal Investigators (PIs) for display on Cancer.gov and ClinicalTrials.gov websites, in order to support investigator and patient searches of oncology trials and provide a point of contact for additional information.
- If an investigator or site public contact is not available,
  - LPO public contact is provided if the site is a member of the LPO, *or*
  - CTSU contact is provided if the site is not a member of the LPO.
- Please note that at this time, the CTEP and CTSU databases do not have the capability of supporting protocol, investigator, or department specific public research contact information.

Public Contact Information (2)

- At the time of initial site registration **Approval** in the Regulatory Support System, participating site and public contact information is provided to the Clinical Trials Reporting Program (CTRP) by the CTSU.
- CTRP provides the participating site and public contact information as follows:
  - To Cancer.gov for all NCI-supported studies;
  - To ClinicalTrials.gov for studies under a CTEP held IND; *and*
  - To the LPO for non-CTEP held IND studies, but the LPO is responsible for updating the information on ClinicalTrials.gov

Public Contact Information (3)

- NCI created a new programming tool* which makes participating site data available to third parties, thereby expanding opportunities for patients and doctors to locate NCI trials
  - Cancer.gov now utilizes this programming tool to enhance searching capabilities
  - As a result of this improved search function, the number of Cancer.gov users is expected to increase and accurate contact information is crucial

**Sites interested in incorporating the programming tool (Application Programming Tool (API)) to enhance their local trial search application can access it at https://clinicaltrialsapi.cancer.gov/v1/*

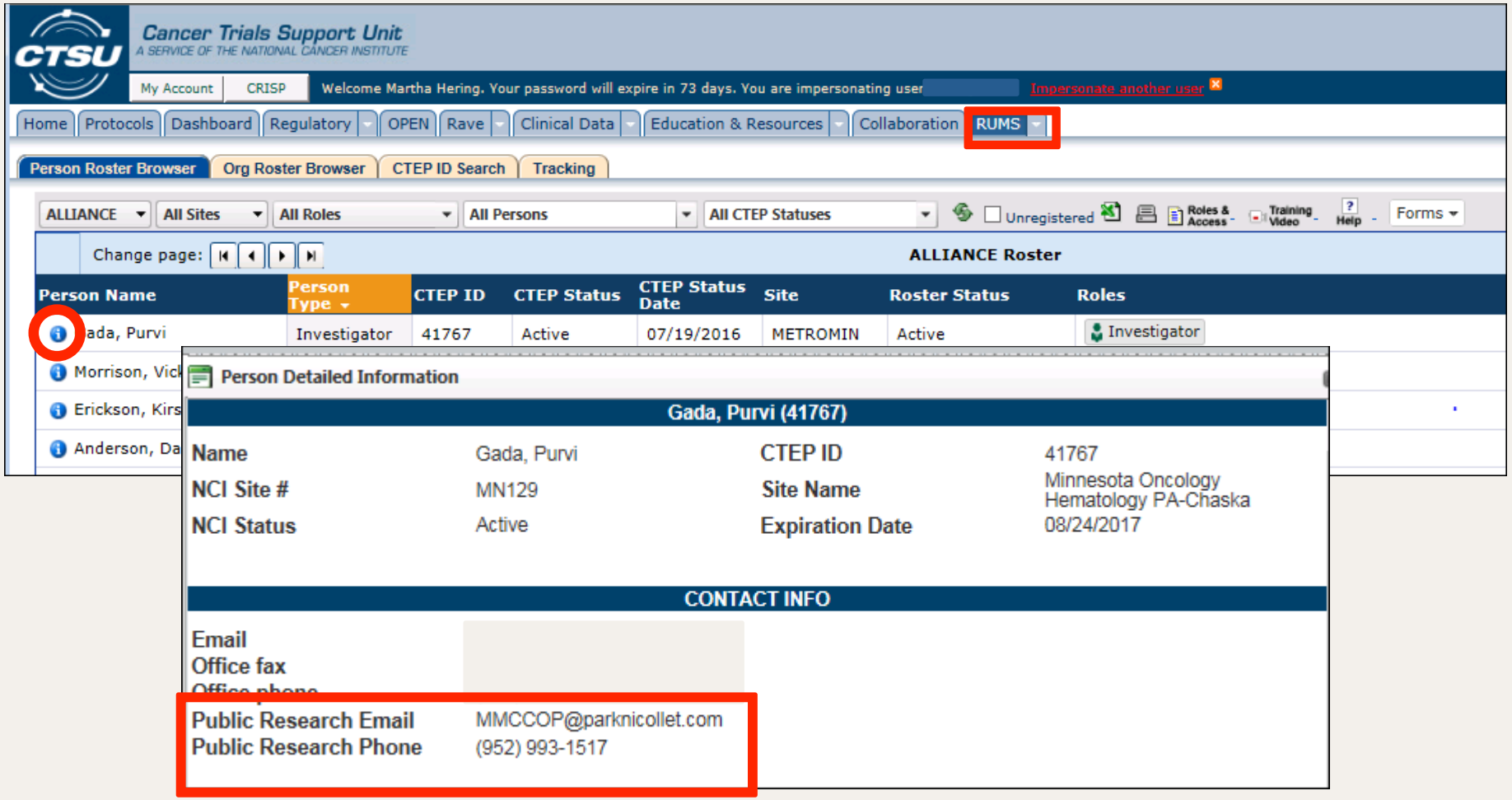
Public Contact Information (4)

- Public feedback supports the use of central public contact information for participating sites to improve the ability of patients and their physicians to ask questions and receive timely responses.
- Central contact information may include:
  - Central Phone No: such as: 1-800-CTR-IALS; and/or
  - Central email address: such as: clinicaltrials@cancercenter.edu

Public Contact Information: What can you do now?

- Check the CTSU website for your current CTEP site codes and their current public research contact information.
- Within your institution, determine the ***single best*** public research phone and public research email for each of your CTEP site codes.
- Remember that ***institution-specific*** public research contact information should apply for ***all*** CTEP and DCP-sponsored studies active at that CTEP site code including:
  - all NCTN adult clinical trials (e.g., ALLIANCE, ECOG-ACRIN, NRG, SWOG)
  - all NCTN pediatric clinical trials (e.g., COG)
  - all NCORP research base clinical trials (e.g., WAKE, URCC), *and*
  - all ETCTN early phase clinical trials (e.g., LAO, EDDOP).

Locating Public Contact Information



Updating Public Contact Information

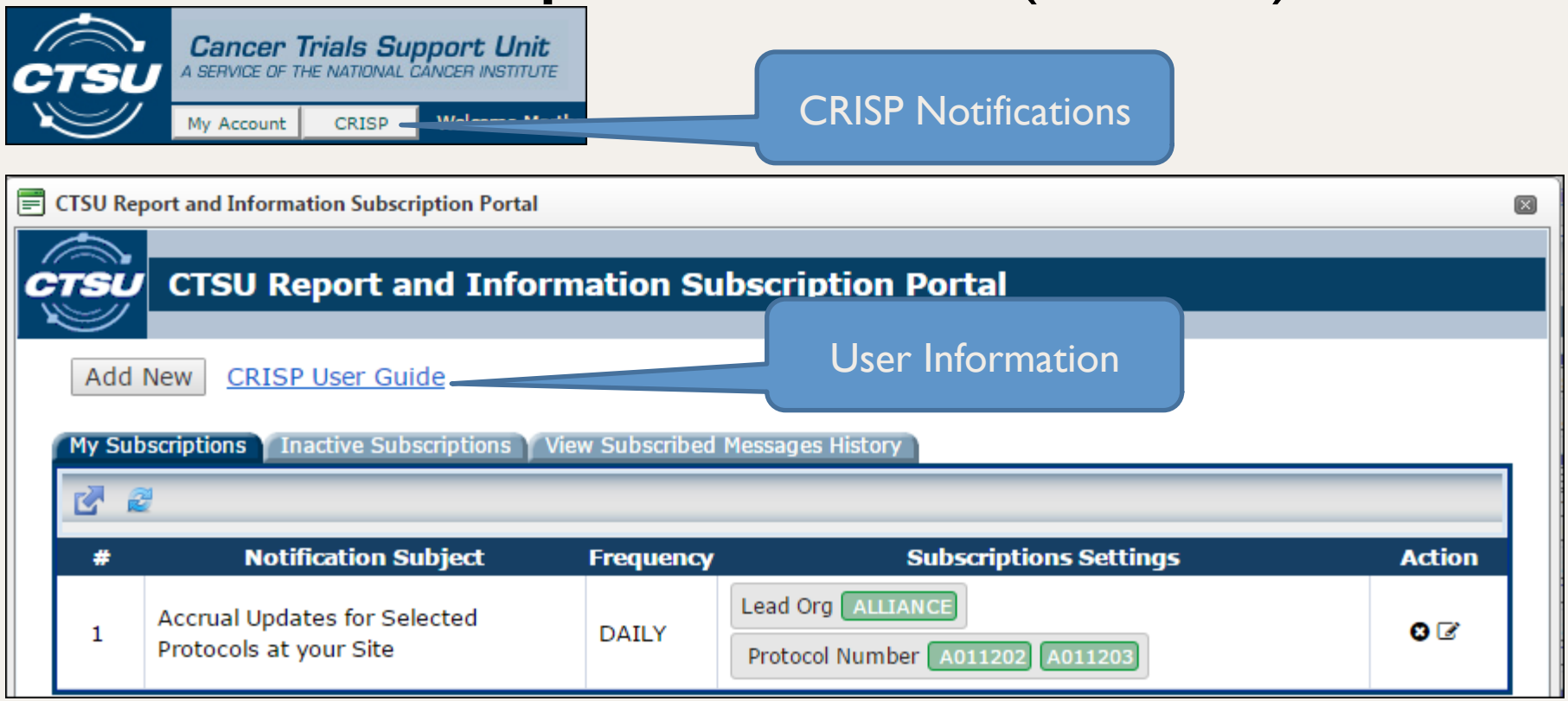
- To update CTEP site code specific public contact information, email CTEP's ECU Help Desk at ecuhelpdesk@mail.nih.gov and provide
  - CTEP site code and name
  - Public research contact phone
  - Public research contact email
- Other Issues
  - Contact the CTSU Help Desk
  - Will assist to identify source of discrepancy and forward to appropriate contact

Public Contact Information - Future Plans

- Support new Cancer.gov search application by encouraging use of central public contacts for an institution such as:
  - Central Phone - 1-800-CLT-RIAL
  - Central E-mail - clinicaltrials@cancercenter.edu
- Enhance the options for maintaining public contact information (e.g., protocol and site specific *or* investigator and site specific).
- Improve visibility of public contact information on the CTSU website.

WEBSITE UPDATES

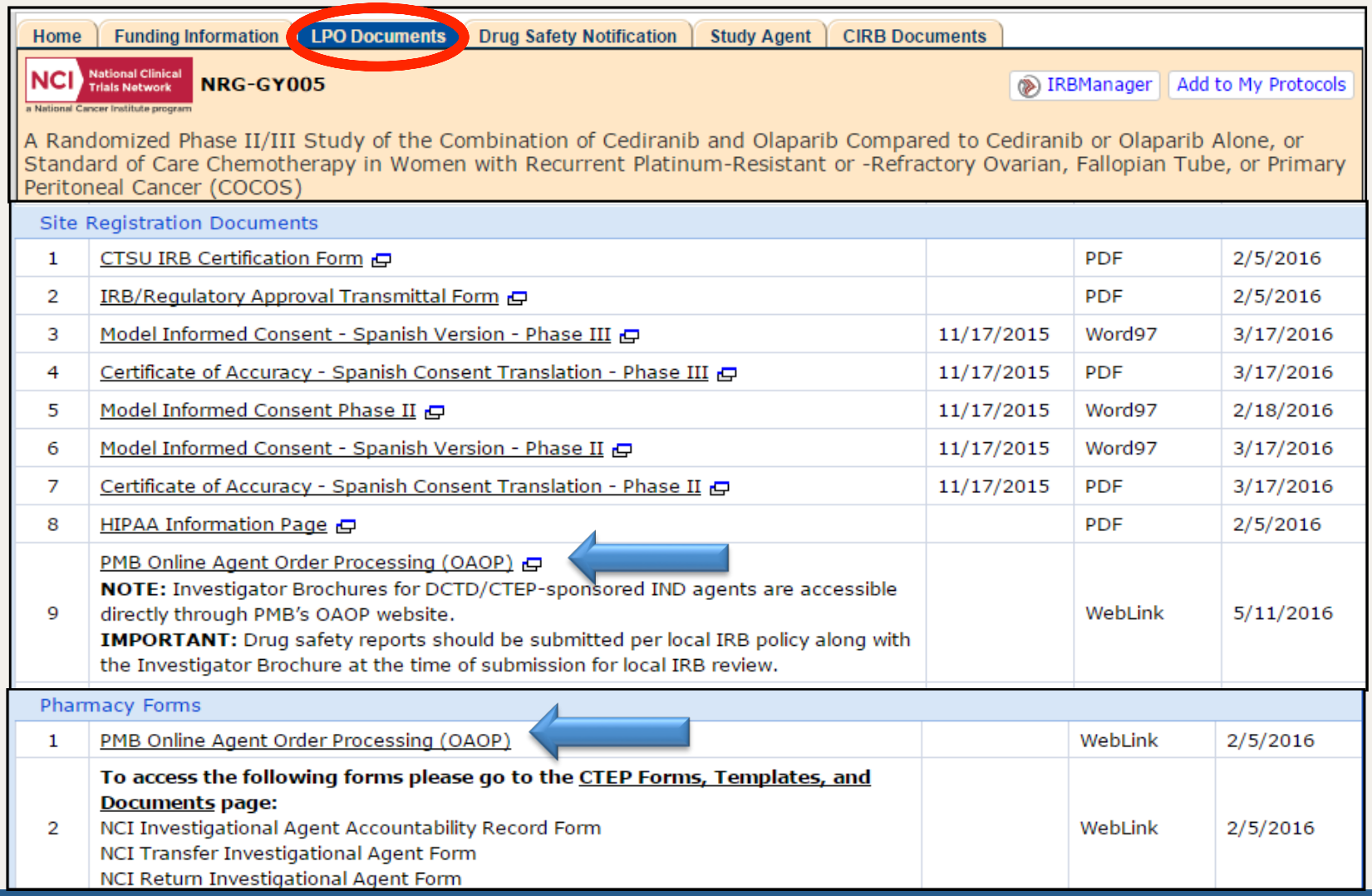
CTSU Report and Information Subscription Portal (CRISP)



New Notifications: Multi-step Accruals at a Site, IRB Approval Received, Site Registration Approval or Change on Selected Protocols, IRB Approval Expiring in 30 Days

Online Agent Order Processing Application (OAOP)

Links are now posted to the Online Agent Order Processing Application (OAOP) for studies that Pharmaceutical Management Branch (PMB) provides agent.



Home | Funding Information | LPO Documents | Drug Safety Notification | Study Agent | CIRB Documents

NCI National Clinical Trials Network — a National Cancer Institute program

NRG-GY005

IRBManager | Add to My Protocols

A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS)

Site Registration Documents

1	CTSU IRB Certification Form		PDF	2/5/2016
2	IRB/Regulatory Approval Transmittal Form		PDF	2/5/2016
3	Model Informed Consent - Spanish Version - Phase III	11/17/2015	Word97	3/17/2016
4	Certificate of Accuracy - Spanish Consent Translation - Phase III	11/17/2015	PDF	3/17/2016
5	Model Informed Consent Phase II	11/17/2015	Word97	2/18/2016
6	Model Informed Consent - Spanish Version - Phase II	11/17/2015	Word97	3/17/2016
7	Certificate of Accuracy - Spanish Consent Translation - Phase II	11/17/2015	PDF	3/17/2016
8	HIPAA Information Page		PDF	2/5/2016
9	PMB Online Agent Order Processing (OAOP) **NOTE:** Investigator Brochures for DCTD/CTEP-sponsored IND agents are accessible directly through PMB's OAOP website. **IMPORTANT:** Drug safety reports should be submitted per local IRB policy along with the Investigator Brochure at the time of submission for local IRB review.		WebLink	5/11/2016

Pharmacy Forms

1	PMB Online Agent Order Processing (OAOP)		WebLink	2/5/2016
2	**To access the following forms please go to the CTEP Forms, Templates, and Documents page:** NCI Investigational Agent Accountability Record Form NCI Transfer Investigational Agent Form NCI Return Investigational Agent Form		WebLink	2/5/2016

Imaging and Radiation Oncology Core (IROC) Credentialing Status Inquiry (CSI) Form

Home | Funding Information | LPO Documents | Drug Safety Notification | Study Agent | CIRB Documents

NCI National Clinical Trials Network — a National Cancer Institute program

NRG-BN001

IRBManager | Add to My Protocols

Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma

Site Registration Documents

1	CTSU IRB Certification Form		PDF	9/15/2015
2	IRB/Regulatory Approval Transmittal Form		PDF	9/15/2015
3	Model Informed Consent (Amendment #1)	8/7/2015	Word97	9/15/2015
4	Model Informed Consent - Spanish Version (Amendment #1)	8/7/2015	Word97	11/12/2015
5	Certificate of Accuracy - Spanish Consent Translation (Amendment #1)	10/16/2015	PDF	11/12/2015
6	HIPAA Information Page		PDF	9/15/2015
7	Memorandum: IND Exempt for Temozolomide		PDF	9/15/2015
8	Radiation Therapy Facility Inventory Form **NOTE:** Sites that are not a member of the lead organization must have a current copy of this form on file with the CTSU Regulatory Office, or submit one indicating participation in the RPC monitoring program, prior to enrolling to this study.		PDF	9/15/2015
9	**NRG-BN001 RTQA Credentialing** **RT Credentialing Requirements**		Plain Text	9/15/2015
10	Complete or Update Your Online Electronic **Facility Questionnaire** (This link will take you to the IROC Houston website).		Plain Text	9/15/2015
11	IROC Credentialing Status Inquiry (CSI) Form **NOTE:** This study has IROC radiation/imaging credentialing requirements. The CSI form must be completed as the first step in the credentialing process.			
12	Phantom Irradiation (This link will take you to the IROC Houston website).		Plain Text	9/15/2015

Start the RT credentialing process here!

Contact Information & Questions

- CTSU Help Desk
  - CTSUcontact@westat.com
  - 1-888-823-5923